DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DEVICE LISTING

Complete and Return Only the Original Form to:
Please do not mail the instruction pages with your form.
Food and Drug Administration
Center for Devices & Radiological Health, HFZ- 308
9200 Corporate Blvd., Rockville, MD 20850-4015

Form Approved: OMB No. 0910-0387
Expiration Date: April 30, 2008

1. TODAY'S DATE *(mm/dd/yyyy)*

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C.331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

2. OWNER/OPERATOR NUMBER

3. OWNER/OPERATOR NAME *(Business name)*

NUMBER AND STREET

CITY | STATE | ZIP CODE

FOREIGN STATE | POSTAL CODE | COUNTRY

4. REGISTRATION NUMBER

5. ESTABLISHMENT NAME *(Business name)*

NUMBER AND STREET

CITY | STATE | ZIP CODE

FOREIGN STATE | POSTAL CODE | COUNTRY

6. LISTING INFORMATION: Number of product codes you are going to list for this establishment:

REASON FOR LISTING: ☐ New Listing ☐ Update to Device Already Listed ☐ Delete Listing

PRODUCT CODE | PMA NUMBER | 510(k) NUMBER

CLASSIFICATION NAME

PROPRIETARY NAME

COMMON OR USUAL NAME

PREVIOUS LISTING NUMBER | LISTING NUMBER

☐ Contract Manufacturer ☐ Manufacturer ☐ Reprocessor of Single Use Devices
☐ Contract Sterilizer ☐ Remanufacturer ☐ Specification Developer
☐ Foreign Exporter ☐ Repackager/Relabeler ☐ U.S. Manufacturer of Export Only Devices

REASON FOR LISTING: ☐ New Listing ☐ Update to Device Already Listed ☐ Delete Listing

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7. SIGNATURE OF OFFICIAL CORRESPONDENT | 8. TYPED OR PRINTED NAME | TITLE

Instructions for Completing FDA Form 2892: Device Listing

All information must be in English. Submit a signed original copy.

Item 1. Today's date - Enter the month, day, and year the form is completed using a MM/DD/YYYY date format.

Item 2. Owner/Operator Number - Fill in if an owner/operator Identification (I.D.) number has been previously issued by the FDA. Leave this space blank if no I.D. number has been issued. FDA will assign an I.D. number after processing and provide this to the official correspondent.

Item 3. Owner/Operator Name & Address - Name - Enter the business name of the corporation, subsidiary, affiliated company, or partnership that is the owner or operator of the registering establishment. Only enter the proprietor's name or an individual's name if no other business name exists. Address - See General Address instructions

Item 4. Registration Number - Fill in if a registration number has been previously assigned by the Food and Drug Administration (FDA). Leave this space blank if no registration number has been issued. FDA will assign a registration number after processing and provide this to the official correspondent.

Item 5. Establishment Name and Address - Name - Enter the legal name of the establishment conducting the regulated activity. Address - See General Address instructions.

Item 6. Number of product(s) that you are going to list for this establishment: Enter the number of product codes that you are now listing on this form. For each of the product codes fill in the following information:

Reason for the Listing: Check the appropriate box. Select only one.

Product Code: Enter the three letter product code that corresponds to the device name assigned to your device, or enter the three letter product code that appears on the 510(k) clearance or PMA approval letter. The device names and product codes appear in an on-line database, www.fda.gov/cdrh/prodcode.html. If you cannot determine the product code, provide the 510(k), PMA or regulation number of the device. Do not confuse the product code with the seven digit regulation number assigned to the type of device classified in the Code of Federal Regulations, Parts 862-892.

All device types classified as exempt from the 510(k) requirements are subject to the limitations of exemptions. Limitations of device exemptions are found in the device classification chapters in 21 CFR xxx.9, where xxx is replaced with Parts 862-892 (e.g., 862.9, 864.9, etc.). It is your responsibility to ensure that you meet the exemption criteria and that your device does not exceed the limitations of exemption. If your device exceeds the limitations of exemption, you must submit a 510(k) and receive a letter from FDA stating that your device may be commercially distributed in the U.S. prior to marketing your device.

PMA Number: Please enter the PMA number found on your Premarket Approval (PMA) letter.

510(k) Number: Please enter the 510(k) number found on your Substantial Equivalency (SE) letter.

Classification Name: Enter the classification name or device name for the generic category of the device. The name can be found in the on-line product classification database, www.fda.gov/prodcode.html. DO NOT ENTER "NONE" OR "MULTIPLE" IN THIS BLOCK. If you are unable to determine your classification name, please leave this item blank and submit a copy of the device labeling and an explanation of the intended use of the product. If you know the name of a similar product, please also provide this information. FDA staff will review the labeling and intended use information and either determine the correct product code, or advise you of any further actions you may need to take.

Proprietary Name: Multiple brand names should be entered. FDA does not issue a separate medical device listing number for each brand name of your device.

Common or Usual Name: If more than one device is being listed under one classification name, enter a descriptive phrase which represents the group of devices, i.e., "Types of Rongeurs", or " X-ray Systems." If one or more devices represented by a classification name is labeled and marketed as "sterile", include the word sterile as part of the common or usual name, i.e., "Sterile and Non-Sterile Syringes."

Previous Listing Number: If this is an update to a previously listed device, please enter the Document Number that appears on the last Device Listing form you submitted for the same product code and establishment registration number.

Establishment Types: Check all that apply. You should only select the establishment type(s) that apply to the operations performed at the establishment you are registering. For example, if the establishment is a manufacturer and specifications developer, but only manufactures the listing device then only check manufacturer.

Please make sure that the codes you select match the establishment type(s) that are on file with FDA in the establishment's registration data. If FDA finds a mismatch, your form will not be processed until you update the establishment's registration data. The listing establishment types are defined as follows.

Contract Manufacturer - Manufactures a finished device to another establishment's specifications and puts device in commercial distribution.

Contract Sterilizer - Provides a sterilization service for another establishment's devices and puts the devices in commercial distribution.

Foreign Exporter - Exports or offers for export to the United States (U.S.), a device manufactured or processed by another individual, partnership, corporation or association in a foreign country, including devices originally manufactured in the United States. A foreign exporter must have an establishment address outside the U.S.

Manufacturer - Makes by chemical, physical, biological or other procedures, any article that meets the definition of "device" in Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Remanufacturer - Processes, conditions, renovates, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or in any way changes the intended use.

Repackager - Packages finished devices from bulk or repackages devices made by another manufacturer into different containers (excluding shipping containers).

Relabeler - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

Reprocessor of Single Use Devices - Performs remanufacturing operations on a single use device.

Specification Developer - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing operations on the device. This includes establishments that in addition to developing specifications also arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

U.S. Manufacturer of Export Only Devices - Manufactures medical devices that are not sold in the U.S. and are manufactured solely for export to foreign countries.

Item 7. Signature of Official Correspondent - The signature of the designated official correspondent.

Item 8. Typed/Printed Name and Title - Type or print the name and title of the designated official correspondent.

General Address Instructions:

Enter the number and street - DO NOT use postal box or rural route numbers.
City - Enter the city in which the owner/operator or establishment is located.
State - Enter the two-character state code of the U.S. Postal Service for the State, territory, or possession.
ZIP Code +4 - Enter the U.S. postal ZIP Code +4 (if known).
Foreign State - Enter the foreign state (i.e., province, prefecture, region, territory) names in which the establishment is located.
Postal Code - Enter the foreign country postal code.
Foreign Country - Enter the full foreign country name.

Public reporting burden for this collection of information is estimated to average .25 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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